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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/211,507	12/14/1998	ALAN R. HIRSCH	054012-0009	9827

22202 7590 01/03/2002

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/03/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/211,507

Applicant(s)
Hirsch

Examiner
Christopher Tate

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 17, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-11, 24-32, 34, 35, and 38-47 is/are pending in the application.
- 4a) Of the above, claim(s) 24-32, 34, 46, and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-11, 35, and 38-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

Applicant's election with traverse of Group I, claims 1, 2, 4-11, 35, and 38-45, in Paper No. 22 is acknowledged. The traversal is on the ground(s) that the independent claims were not newly added but were pending dependent claims that were merely rewritten as independent claims. This is not found persuasive for the reasons set forth in the previous Office action which are restated below.

The methods of Groups I-V are directed to distinct inventions which, as clearly evidenced by the claims and disclosure, do not necessarily require the same odorant be employed and/or all of the steps recited by the other Groups. For example, the method of Group I only requires a single step: the inhalation of an undefined amount of an odorant (such as the odorants recited in claim 1 - which do not include a floral aldehydic perfume odorant, but which is required of the methods of Groups IV and V) that alters vaginal blood flow by a female individual. The method of Group II requires the step of determining a level of sexual arousal of the female individual to manual genital manipulation, to masturbation, or both - which is not required of the other Groups. The method of Group III requires the step of measuring a baseline blood flow to the vagina of the female individual - which is not required of the other Groups. The method of Group IV requires that a floral aldehydic perfume odorant be inhaled and that it increase blood flow to the vagina and the method of Group V requires that a floral aldehydic perfume odorant be inhaled and that it decrease blood flow to the vagina, which are not necessarily required of Groups I-III. The methods of Groups IV and V, as clearly evidenced by the claims themselves,

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are independent and distinct, each from the other, since they have different modes of operation, they have different functions, and they have different (and opposite) effects. The search for each of the above inventions is not co-extensive particularly with regard to the literature search.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-11, 35, and 38-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing and/or decreasing blood flow to the vagina via inhaling the particular commercial odorants (see, e.g., page 12, lines 1-13 of the instant specification) and/or mixtures thereof instantly demonstrated, does not reasonably provide enablement for a method of increasing and/or decreasing blood flow to the vagina via inhaling any undefined odorant therein and/or the subjective odorants instantly claimed (see, e.g., claims 1, 2, 4, 5, 7-11, 35, 38-43, and 45 - see USC 112, 2nd paragraph rejection below with respect to these claims). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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Based upon Applicant's response and Declaration of July 6, 2001, it is deemed that Applicant has reasonably demonstrated that the particular commercial odorants (see, e.g., page 12, lines 1-13 of the instant specification) act to alter blood flow to the vagina via inhaling an effective amount thereof. However, the claims encompass such unusual use via inhaling any undefined odorant and/or the subjective odorants instantly claimed (see, e.g., claims 1, 2, 4, 5, 7-11, 35, 38-43, and 45) which is clearly beyond the scope of the instantly disclosed invention. The instantly claimed odorants are highly subjective with respect to the actual odors being encompassed and, thus, are not enabled - e.g., based upon the ingredients within a given recipe of pumpkin pie or banana nut bread, numerous distinct odors particular to that given recipe would be emitted therefrom. This is also the case for baby powder, which is actually talc to which a particular perfume is added and which varies by commercial manufacturer; and is also the case for cucumber (e.g., based upon the brand, species, age/ripeness, geographic location in which it is grown, etc.), licorice-based odorants (e.g., Good and Plenty® candy has a distinct odor from that of some other licorice based products such as anise), chocolate (e.g., milk chocolate has a distinct odor from dark chocolate), cherry odorants (e.g., cherry pie has an odor distinctly different from cherry cough drops), charcoal barbecue smoke odorant is exceptionally ambiguous as this could potentially be defining numerous distinct odors (what actually is a charcoal barbecue smoke odor - e.g., is it smoked barbecued meat odor, smoked barbecue sauce containing various spices, or something else?). In addition, it is noted in several instances that using the same odorant or mixture of odorants that cause an increased blood flow to the vagina to some females also cause

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a decrease in blood flow to the vagina in other females. Further, as disclosed by Doty (Philadelphia Sensorics, 1983), there are numerous variables such as an individual's occupation, general health, psychological state, and age which play a role in assessing sensory function of smell (see, e.g., pages 16-18). Therefore, altering blood flow to the vagina via the inhalation of such odorants, including the undefined and/or broadly defined odorants instantly claimed, as well as any undefined amounts thereof, is considered to be highly unpredictable between females based upon such variables.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use an odorant having having the unusual disclosed/claimed functional effect, other than inhaling one of the particular demonstrated commercial odorants or mixtures thereof, in an amount effective to provide the claimed alteration in blood flow to the vagina.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-11, 35, and 38-45 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The metes and bounds of the undefined or subjective odorants recited in claims 1, 2, 4-11, 35, and 38-45 are not clearly nor adequately delineated making the claims unclear. For example, based upon the ingredients within a given recipe of pumpkin pie or banana nut bread, numerous distinct odors particular to that given recipe would be emitted therefrom. This is also the case for baby powder, which is actually talc to which a particular perfume is added and which varies by commercial manufacturer; and is also the case for cucumber (e.g., based upon the brand, species, age/ripeness, geographic location in which it is grown, etc.), licorice-based odorants (e.g., Good and Plenty™ has a distinct odor from that of some other licorice based products such as anise or other products having licorice as a base in combination with other ingredients), chocolate (e.g., milk chocolate has a distinct odor from dark chocolate), cherry (e.g., cherry pie has an odor distinctly different from cherry cough drops), charcoal barbecue smoke odorant is exceptionally ambiguous as this could potentially be defining numerous distinct odors (what actually is a charcoal barbecue smoke odor - e.g., is it smoked barbecued meat odor, smoked barbecue sauce containing various spices, or something else?). The subjective nature of the recited odorants (any of which is deemed essential in terms of adequately defining these particular active ingredients within the claimed article of manufacture) causes these claims to be very ambiguous and unclear.

Claims 10 is rendered vague and indefinite by the phrase "wherein the concentration of the odorant is at about 25-55 decismel units" because it is unclear as to what this concentration level relates to - e.g., is this the level of decismel units within each unit dosage or just a level of odorant in some initial odorant preparation from which such dosage units are prepared from?

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-11, 38, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Doty (Philadelphia Sensorics, 1983) with evidence provided by Sweeny et al. (US 4,493,869), as well as the recognized state of the art.

Doty et al. teach an article of manufacture known as Microfragrance samplesTM (which is a registered trademark of the 3M Corporation, St. Paul, Minnesota) comprising microencapsulated odorants including cherry odorant and licorice odorant therein (see, e.g., pages 3-5, Experiment 1, pages 6-7 including Figure 2) which were administered to female participants via inhalation (see, e.g., page 4, first full paragraph) for apparently a short duration (thus about within the short time range claimed). As evidenced by Sweeny et al. (an inventor with the 3M Corporation), the Microfragrance samples disclosed by Doty et al. are contained within a manufactured article whereby the odorant is released by rupturing the microcapsules therein - e.g., a scratch and sniff type odor patch article (see, e.g., col 1, lines 62-68, and col 3, lines 6-10).

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In addition, with respect to claim 5, it is well recognized in the baby powder art that women applying baby powder to their babies (which typically is done within about the time period instantly claimed) would inherently and necessarily inhale a substantial amount of baby powder odor. It is also well recognized in the food art that a substantial amount of charcoal barbecue odor would inherently and necessarily be inhaled by women during the cooking and/or eating of food (e.g., meat) comprising such an odor. Thus, the one-step methods of claims 5-11, 38, and 44 are deemed to be anticipated by such art-recognized acts.

Please note that the concentration and/or decismel units (which appears to be a unit of measure seldom used in the odorant art other than by applicant) instantly claimed fails to define what they relate to with respect to the claimed unit dosage and, as such, the Microfragrance samples of Doty are (at the least) deemed to contain such a level at some point (e.g., within the initial fragrance prior to incorporating into the Microfragrance samples, and/or within each of the scratch and sniff sample packs themselves). Further, since there are no recited conditions with respect to administering the odorant so as to effect an increase and/or decrease of blood flow to the vagina by the claimed percentage ranges, the inhalation thereof would inherently bring about such an effect (e.g., at some point - perhaps after inhaling for minutes or hours) at least in some female individuals, especially given the extreme variability of the blood flow effects on different females caused thereby, as instantly disclosed.

Therefore, the cited reference and/or the recognized state of the art, is deemed to anticipate the instant claims above.

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Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached at (703) 308-4743. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1651 is (703) 308-4242.



Christopher R. Tate
Primary Examiner, Group 1651